

Concept Note:

First Consultative Meeting: 14th September 2020

COVID-19 Vaccine in Pakistan

COVID-19, the Pandemic that emerged in the city of Wuhan, China in late December 2019. First two cases were reported in Pakistan on 26th February 2020. In March, WHO declared it as global pandemic. Its devastating impact on health systems has pushed countries to their limits. The initial response for this emergency is immediate healthcare buildup, strict implementation of standard operating procedures (non-pharmacological interventions), while delineating the sustainable strategy to control the pandemic. One of the sustainable approach for prevention and control of COVID-19 is an effective COVID-19 vaccine. There is a need to have robust program with foresight on scientific evidence for vaccine safety, efficacy, availability, management and distribution in the coming months/years. Therefore, National Command and Control Centre (NCOC) for COVID19 has commissioned “National Expert Committee for COVID19 Vaccine” to work on a National Vaccine Strategy.

So far, there is no effective vaccine against SARS-COV2 Virus. The genetic sequence of SARS-CoV-2, the coronavirus, that causes COVID-19, was published on 11 January 2020.^{A,B} It triggered an intense global research and development (R&D) competition to develop the vaccine, and as a result, it is squeezing the average vaccine development time of 10-11 years into 1.5-2 years. More than 250 COVID-19 vaccine candidates are being pursued globally. As per the World Health Organization landscape, 139 candidates are in pre-clinical evaluation and 26 were in different stages of clinical trial until 31st July 2020^A. Some companies are claiming to make vaccine available between the fourth quarter of 2020 and the first quarter of 2021. Amid this competition, accessing correct data is a challenge. More recently, many countries have claimed achieving success for COVID-19 vaccine, however, this appears more of a political rhetoric than a scientific proclamation.

Vaccine or any biological product can be allowed in Pakistan, only when it is approved by the national regulators. Drug Regulatory Authority of Pakistan (DRAP) is the regulatory body with all its related Departments in place starting from the approval of vaccines clinical trials, emergency use authorization, and regulator permission for general use by the public. Under this mandate, DRAP pro-actively guide processes, publish framework, establish separate Board, introduce protocols for clinical trials and expedite potential approval of COVID19 vaccines. The issues of vaccine safety, efficacy, side effects will only be determined after clinical trial phase III. Therefore, a clear checklist for phase III trial data is necessary pre-requisite before its approval.

Once proven successful, the ultimate goal of vaccination is to make it available for everyone. When released, its supply is expected to be limited initially, giving rise to questions about its access to the needy and most vulnerable and essential groups in Pakistan. Also, costs of vaccine production; procurement; quantity and long-term efficacy are expected to be additional limiting factors for its availability to all. Robust logistics and distribution plan can ensure smooth and timely access of vaccine to the targeted groups. Hence, up-scaling and up-grading the storage facilities of existing infrastructure of EPI can meet the needs of COVID19 vaccine storage. Current expanded program on immunization (EPI) collaborates with the District Health officials (DHO) for routine vaccination of polio, measles, typhoid. The COVID-19 vaccine can be administered in a similar manner. With predefined protocols, DHOs can engage secondary and tertiary care hospitals to administer the COVID-19 vaccines.

The effective risk communication strategy should be in place for COVID-19 vaccination to educate end users, gauge perceived risk, provide actionable information to the targeted groups. The awareness campaigns that leverage the community leaders, health associations, public healthcare infrastructure and private sector should be part of the communication planning and implementation framework.

Indigenous capacity building ranges from vaccine packing, filling, partial production and complete indigenous production. Complete indigenous production can make Pakistan self-sufficient in immunizing its population and managing future preventative diseases. National Institute of Health, (NIH) produces traditional vaccines in limited capacity using basic technology. The private sector and NIH produce vaccines by secondary manufacturing, where vials are produced after filling, labelling and packing using the imported bulk concentrate. Existing capacity of vaccine packing and filling in public and private sectors in Pakistan could be developed with clear framework, outcome-based incentives, trained human resource, improved academic linkages and technology transfer facilitation. Clear framework of NIH academic collaborations and public private partnerships can increase country capacity for affordable vaccines production.

Pakistan needs to develop its capacity for conducting clinical trials of pharmaceuticals. The COVID-19 pandemic can be a potential opportunity to conduct clinical trials (in collaboration with other countries, where needed) and focus on developing its own capacity as per international standards. Establishing linkages with vaccine manufacturers and academia to conduct clinical trial research should be led by subject experts in clinical trials, vaccine, biologics and drug development for sustainable capacity building. This will train our local scientists, facilitate technology transfer and linkages with global institutes. Some renowned international institutions have already shown interest in conducting phase III trials in Pakistan and the Ministry of National Health Services Regulation and Coordination is making due progress in this regard. However, such collaborations need to ensure patient safety, clinical trials protocols and other ethical considerations to be safe guarded through adequate legislative framework.

Once COVID-19 vaccine becomes available, the prioritized segments for vaccination should be essential workers in healthcare, law enforcement agencies (LEA), staff at point of entries, elderly, people with comorbidities, immunocompromised, COVID-19 victims adult family members, retail shoppers, teachers, judiciary, banking, airline and public transport personnel specially those above 50 years of age.

Priority actions and plans should be clearly defined for vaccine management. Pakistan should work on multiple avenues to secure vaccine supply. One of them is to negotiate with leading manufacturers to secure vaccines at the earliest, for its most prioritized group of population. Efforts are on the way to explore the potential to secure vaccine supply for the portion of population. Possible international collaborations can be capitalized for technology transfer, academic exchange and training local manpower.

Some specific questions for deliberation of stakeholders are listed below:

1. How should the communication strategies be shaped and developed, knowing the perception challenges of COVID-19 vaccine?
2. What is needed to develop fast-track transparent system for approval and registration of COVID-19 vaccine?

A. National Covid-19 Vaccine Strategy for Pakistan, Report by COVID Vaccine Expert Committee.

B. Government of Pakistan Anti COVID-19 Strategy, Ministry of National Health Services Regulation and Coordination.